APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 16,225

DYESTUFFS AND CHEMICALS, INC., *Petitioner*,

v.

ARTHUR S. FLEMMING, Secretary of Health, Education, and Welfare, *Respondent*.

Petition for Judicial Review of an Order Under the Federal Food, Drug, and Cosmetic Act

[October 30, 1959]

Earl Susman and Paul C. Warnke (Susman, Mayer & Willer and Covington & Burling were with them on the brief) for Petitioner.

William W. Goodrich, Assistant General Counsel, Department of Health, Education, and Welfare (Malcolm R. Wilkey, Assistant Attorney General, Robert S. Erdahl and Harold P. Shapiro, Attorneys, Department of Justice, and Robert H. Becker, Attorney, Department of Health, Education, and Welfare, were with him on the brief) for Respondent.

Before GARDNER, VOGEL and VAN OOSTERHOUT, Circuit Judges.

VOGEL, Circuit Judge.

Petitioner, Dyestuffs and Chemicals, Inc., herein seeks judicial review of an order promulgated by the respondent, Secretary of Health, Education, and Welfare, 24 F.R. 883, entitled "In the matter of amending the color-certification regulations with respect to FD&C Yellow No. 1, FD&C Yellow No. 2, FD&C Yellow No. 3 and FD&C Yellow No. 4." Jurisdiction of this court to review the order complained of is based upon 21 U.S.C.A. § 317 (f) (1).

21 U.S.C.A. § 346 (b) (§ 406 (b) of the Federal Food, Drug and Cosmetic Act) provides that:

> "(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmful diluents."

Petitioner is a producer of food colors, including certain coal tar colors known as FD&C Yellows 3 and 4 which have been widely used in the coloring of edible fat products, principally butter and oleomargarine. FD&C Yellows 3 and 4 have been certified by the respondent and his predecessors under § 346 (b) as safe for such use for approximately the past 40 years. On January 24, 1957, the Deputy Commissioner of Food and Drugs published in the Federal Register, 22 F.R. 478, a notice of his proposal to amend the Food and Drug Administration regulations by removing FD&C Yellow Nos. 1, 2, 3 and 4 from the approved list for unrestricted use. This notice solicited the views and comments of interested parties. After receiving comments, including those of the Certified Color Industry Committee of which petitioner is a member, the Commissioner on May 4, 1957, published an order removing the colors in question from the approved list, 22 F.R. 3173, because they "are not harmless and suitable for use within the meaning of" 21 U.S.C.A. § 346 (b). Such order was to become effective 90 days after publication unless stayed by the filing of proper objections. On May 27, 1957, within the time provided by law, the Certified Color Industry Committee filed objections to the order and requested a hearing thereon in accordance with the provisions of 21 U.S.C.A. § 371 (e) (2) (3). The objections, which will be subsequently discussed in more detail, were mainly on the ground that the term "harmless" had long been judicially and administratively construed to mean "harmless and suitable for use in food" *under the in-*

tended conditions of their use and that petitioner's product could so qualify *when used within certain stated tolerances.*

Pharmacological studies conducted in the Food and Drug Administration's scientific laboratories had established that the colors in question were toxic when fed to laboratory animals, in that, while they produced no adverse physiological effects at 500 parts per million (0.05%) of the test animals' diets, they did produce such adverse effects at 1,000 ppm (0.1%) in the test diets. These studies and experiments formed the basis for the Deputy Commissioner's order of January 24, 1957, removing the coal tar colors in question from the harmless list.

After the objections were filed, a conflict arose between two Courts of Appeals over the construction of § 346 (b) as applied to the use of red coal tar colors. The 2nd Circuit, in *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare*, 1956, 236 F.2d 866, sustained the power of the Secretary to delist those colors where laboratory tests showed that their addition to food might be injurious to health. The 5th Circuit, however, in *Florida Citrus Exchange* v. *Folsom*, 1957, 246 F.2d 850, held to the contrary and concluded that the Secretary could certify red coal tar colors for use in food on the basis of tolerances within which their use was harmless. Pending a resolution of this conflict by the Supreme Court, the delisting of the colors was stayed by administrative action, 22 F.R. 6612, August 17, 1957.

On December 15, 1958, the Supreme Court, in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 166, 167, reversed the holding of the 5th Circuit and in effect sustained that of the 2nd Circuit by holding that "where a coal-tar color is not harmless, it is not to be certified" and, therefore, that the Secretary "is without power to permit the use of harmful coal-tar colors in specific foods through a system of tolerances."

On February 6, 1959, the Deputy Commissioner, without a hearing as provided for in 21 U.S.C.A. § 371 (e) (2) (3), published the final order delisting the colors in question. The order explained the failure to grant a hearing as follows:

> "The Supreme Court's (*Flemming* v. *Florida Citrus Exchange*, supra) decision having established the proper construction of the law, the objection of the Certified Color Industry Committee to the delisting of FD&C Yellow Nos. 1, 2, 3, and 4 is without substance, and no purpose could be served by holding a public hearing. The Department has no authority to certify colors that are themselves toxic, as is the case with FD&C Yellow Nos. 1, 2, 3, and 4, and the Department has no authority to establish a tolerance for such a color, as requested by the Industry Committee."

In this appeal, the petitioner requests that this court:

> "1. Review and set aside the Respondent's Order of February 6, 1959, insofar as it affects the production, sale and use of FD&C Yellows 3 and 4 for coloring edible fats, as being unsupported by substantial evidence of record adduced at a public hearing; and that the Court order the Respondent to hold a public hearing as required by the Federal Food, Drug, and Cosmetic Act; and
>
> 2. Direct that there be full consideration at such hearing of the effect of legislation enacted by Congress and proposed by Respondent since the decision in *Flemming* v. *Florida Citrus Exchange*, *supra*, in establishing the principle that coal tar colors may be approved under conditions appropriate to assure the safety of such use."

Petitioner's first contention is that the respondent's refusal to hold a public hearing invalidates the order. 21 U.S.C.A. §§ 371 (e) (2) (3) provide that:

> "(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any persons who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. * *
>
> (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. * * *"

Petitioner contends that the foregoing constitute an unconditional statutory requirement for a hearing upon the filing of objections and that they were wholly disregarded by the order deleting the colors from the harmless list, with the result that no chance was afforded petitioner and others to raise any objections that might be available or to question and refute the pharmacological evidence referred to in the Secretary's order.

Respondent counters by claiming that the grounds set forth in petitioner's objections were wholly insufficient

to warrant a hearing in that they sought the promulgation of regulations that were beyond the Department's authority.

Petitioner's "grounds for objection" were four in number. The first asserted that, "The colors affected by the order serve a useful and desirable purpose in coloring food and drugs," and that they had been so used for many years, principally with margarine and butter. Objection No. 2 alleged:

> "The evidence of potential injury from the use of FD&C Yellow Nos. 1, 2, 3 and 4 is inadequate to justify the order. Although there has not been any report of injury to humans from any of the four colors (as acknowledged by the Commissioner in a public statement of January 23, 1957), the order will prohibit their use in foods and internal drugs and cosmetics solely on the basis of pharmacological tests on animals in which the ingestion of massive doses of FD&C Yellow Nos. 1, 3 and 4 over long periods of time.
>
> (a) produced no adverse physiological effects at a concentration of 500 ppm (0.05%) of the animals' total diet; but
>
> (b) but produced some adverse physiological effects at a concentration of 1,000 ppm (0.1%) of the animals' total diet.
>
> The 'no-ham' level thus shown (500-1,000 ppm) is so far in excess of the level of actual use in the human diet that those results do not afford any basis for the order."

Objection No. 3 asserted that:

> "The reasonably anticipated uses of the four yellow colors do not justify any fear of injury from their use. * * *"

Objection No. 4:

"* * * urges that the Commissioner take action to prohibit such excessive concentrations, rather than to bar the proper and harmless use now being made of the colors."

It seems to us obvious, as it did to the respondent, that under the holding of the Supreme Court in *Flemming* v. *Florida Citrus Exchange*, supra, each of the objections set forth by the petitioner must be held inadequate to prevent the removal of the coal tar colors in question from the "harmless" list. Objection No. 1 merely asserts usefulness and desirability. While No. 2 alleges that the evidence of potential injury is inadequate to justify the order, it is based upon the contention that "the 'no-harm' level thus shown (500-1,000 ppm) is so far in excess of the level of actual use in the human diet that those results do not afford any basis for the order." No. 3 asserts that the reasonably anticipated uses do not justify fear of injury; and No. 4 suggests that the Commissioner do what the Supreme Court held he had no authority to do in *Flemming* v. *Florida Citrus Exchange*, supra. Therein, at page 163, the court stated:

"We are not persuaded by the respondents' argument, adopted by the Court of Appeals, that the words 'harmless' and 'poisonous' are relative words, referring not to the effect of a substance *in vacuo* but to its effect, taken in a particular way and in particular quantities, on an organic system. Of course this is so, but the question before us certainly does not depend on it. This is not a case like the examples put which remind us that pure water would be deleterious if taken at the rate of four gallons an hour or common table salt at several ounces. The color substances appear to have been administered at toxicologically significant levels; they played a relatively small part in

the diets of the test animals, generally less, and frequently much less, than 1%. Obviously if the color substances themselves are made an item of diet in the trifling percentages used on the test animals, their effect is poisonous. Congress may have intended 'harmless' in a relative sense, but we think it was in relation to such laboratory tests as the one the Secretary performed that Congress was speaking when it required that coal-tar colors be 'harmless'. *We do not believe that Congress required the Secretary first to attempt to analyze the uses being made of the colors in the market place, and then feed them experimentally only in the proportions in which they appeared in certain of the food products in which the colors were used. This appears to be the very procedure on which Congress turned its back in the 1938 Act.*" (Emphasis supplied.)

And at page 166:

"The Secretary contends that he is without power to permit the use of harmful coal-tar colors in specific foods through a system of tolerances. We believe he is correct."

And finally at page 167:

"*The command of the statute is plain: where a coal-tar color is not harmless, it is not to be certified; if it is not certified, it is not to be used at all.* In this regard also, an approach in terms of the toxicity of the coloring ingredient, rather than of the food product as a whole was chosen by Congress. It evidently took the view that unless coal-tar colors were harmless, the considerations of the benefits of visual appeal that might be urged in favor of their use should not prevail, in the light of the considerations of the public health." (Emphasis supplied.)

We thus conclude that the four grounds set forth in the petitioner's objections to the order were legally insufficient and turn next to the question of whether a hearing must be held even though the prerequisite objections fail to state valid or legal grounds for the requested action.

It will be noted that 21 U.S.C.A. § 371 (e) (2) provides that objections may be filed "* * * stating the grounds therefor, and requesting a public hearing upon such objections * * *" and (3) "* * * the Secretary, after due notice, *shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections.*" (Emphasis supplied.) It is only after filing objections and "* * * stating the grounds therefor, and requesting a public hearing upon such objections * * *" that an interested party is entitled to a hearing. The hearing is solely for the purpose of receiving evidence "relevant and material to the issues raised by such objections". Certainly, then, the objections, in order to be effective and necessitate the hearing requested, must be legally adequate so that, if true, the order complained of could not prevail. The objections must raise issues". The issues must be material to the question involved; that is, the legality of the order attacked. They may not be frivolous or inconsequential. Where the objections stated and the issues raised thereby are, even if true, legally insufficient, their effect is a nullity and no objections have been stated. Congress did not intend the governmental agencies created by it to perform useless or unfruitful tasks. If it is perfectly clear that petitioner's appeal for a hearing contains nothing material and the objections stated do not abrogate the legality of the order attacked, no hearing is required by law.

Support for this conclusion is substantial. In *United States, et al.* v. *Storer Broadcasting Co.*, 1956, 351 U.S. 192, an application was made by the broadcasting company to the Federal Communications Commission for approval

of the company's acquisition of a sixth television station, despite the fact that the regulations allowed the ownership of only five. In holding that the Commission could deny the application without the hearing provided for under the controlling act, the court stated:

> "We agree with the contention of the Commission that a full hearing, such as is required by § 309 (b), n. 5, *supra*, would not be necessary on all such applications. As the Commission has promulgated its Rules after extensive administrative hearings, it is necessary for the accompanying papers to set forth reasons, sufficient if true, to justify a change or waiver of the Rules. We do not think Congress intended the Commission to waste time on applications that do not state a valid basis for a hearing. If any applicant is aggrieved by a refusal, the way for review is open." 351 U.S. at 205.

Similarly, in *Denver Union Stock Yard Co.* v. *Producers Livestock Marketing Assn.*, 1958, 356 U.S. 282, the court held a hearing unnecessary where regulations issued by a producer's association were invalid on their face under the Packers and Stockyards Act. In so doing, the court explained:

> "It is, of course, true that § 310 of the Act provides for a 'full hearing' on a complaint against a 'regulation' of a stockyard. That was also true of the Act involved in *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192. But we observed in that case that we never presume that Congress intended an agency 'to waste time on applications that do not state a valid basis for a hearing.'" 356 U.S. at 287.

Finally, in *Sun Oil Co.* v. *Federal Power Commission*, 5 Cir., 1958, 256 F.2d 233, cert. denied 358 U.S. 872, the court stated:

"We come then to the final question of whether the failure of the Commission to give *Sun* notice and hold formal hearing before rescinding its rate schedule filings and cancelling its certificates of public convenience and necessity requires the setting aside of the Commission's orders. Although *Sun* urges to the contrary, we do not think there was any fact question involved and hence no evidence would have been material. If the question was more than a question of administrative policy, and we doubt that it was, it was a question of law. We do not believe there was a case of an adjudication which was required by the statute 'to be determined on the record after opportunity for an agency hearing' where notice is required by the Administrative Procedure Act. 5 U.S.C.A. § 1004. Nor do we think that the absence of notice has deprived *Sun* of due process as guaranteed by the Constitution. The only benefit that would have inured to *Sun* by notice and hearing would have been the privilege of making a legal argument before the Commission. We find no requirement in the Natural Gas Act for notice and hearing in such a situation." 256 F.2d at 240.

We hold that the respondent was correct and that no hearing need be held when the prerequisite objections are not supported by grounds legally sufficient to justify the relief sought.

Petitioner here also contends that the respondent's order is not supported by substantial evidence of record and hence may not be sustained. In so contending, petitioner overlooks the fact that the requirement that the order be based upon substantial evidence of record is found in 21 U.S.C.A. § 371 (e) (3). That section is not invoked until "objections" have been filed and, as we have heretofore indicated, no "objections" can be deemed to have been

filed when the grounds therefor raise no issues material to the legality of the disputed order.

Petitioner's second contention is that any hearing ordered should be required to include consideration of the legislative and administrative action which followed the Supreme Court's ruling in *Flemming* v. *Florida Citrus Exchange*, supra, as bearing upon the application of that decision to the certifiability of FD&C Yellow Nos. 3 and 4. As we have already determined that no hearing need be held, this point must obviously fail. Moreover, we find nothing contained in those subsequent events which alters our basic conclusion that petitioner is not entitled to a hearing.

The legislative and administrative history to which petitioner calls our attention is as follows: On November 10, 1955, the Secretary of Health, Education, and Welfare removed FD&C Red 32 which had been used in coloring green oranges from the list of certified coal tar colors because of its toxicity. This action led to the previously noted judicial appeals in the 2nd and 5th Circuits and eventually to the decision of the Supreme Court in *Flemming* v. *Florida Citrus Exchange*, supra, in December of 1958. Prior to this, however, on July 7, 1956, Congress, in response to the Secretary's order of November 10, 1955, amended 21 U.S.C.A. § 342 (c) under which the delisting had been required, to provide for temporary certification of Red 32 until March 4, 1959. The Supreme Court in its decision stated that this legislative action, because of its temporary character, did not make the issue of the validity of the delisting of Red 32 moot. Subsequent to this special legislation the color industry developed a substitute color for Red 32 known as Red 2 which was of a lower toxicity, but which was still not certifiable under the general, unamended provisions of 21 U.S.C.A. § 342 (c). On March 17, 1959, Congress extended the emergency legislation for the use of color additives for oranges to Sep-

tember 1, 1961, with the only change being that Red 2, rather than Red 32, was to be used under safe tolerances. Public Law 86-2, 86th Congress. Prior to the passage of this latter legislation, the Secretary, in letters of January 29, 1959, and February 16, 1959, to the hearing committees of the Senate and House respectively, approved the extension of the emergency acts and stated the Department's approval of previously proposed but unenacted legislation of general application embodying the use-under-safe-tolerances principle. Legislation to this effect was again introduced in the recently concluded session of Congress but was similarly not acted upon. H. R. 7624; S. 2197.

Petitioner points out that in *Helvering* v. *Hallock*, 1940, 309 U.S. 106, the Supreme Court reconsidered and abandoned its previous reading of a statutory provision and that it did so despite the government's argument that the *lack* of remedial Congressional action evidenced *approval* of the prior statutory construction so as to debar its judicial reexamination. Petitioner then argues:

> "Here, however, such reexamination not only is not barred but is strongly indicated in view of the positive legislation and direct administrative action already taken to avoid an unworkable interpretation of the coal tar color provisions of the Food, Drug, and Cosmetic Act,"

and that the meaning of the phrase "harmless and suitable for use in food" as it bears on petitioner's products should be construed in the light of these developments. Petitioner's argument is footless and can get nowhere. This court may not extend "judicial reexamination" to the Supreme Court's opinion in *Flemming* v. *Florida Citrus Exchange*, supra, on the basis of proposed Congressional legislation. *Wong Yang Sung* v. *McGrath*, 1950, 339 U. S. 33, 47. As to the specific legislation which granted

temporary relief from the Secretary's order removing Citrus Red No. 32 from the list of certified colors, the Supreme Court was aware of the earlier act to this effect passed in 1956 and found it without bearing on its decision. We reach the same conclusion in respect to the later legislation.

The order of which review is sought is affirmed.

A true Copy.

Attest:

Clerk, U. S. Court of Appeals, Eighth Circuit.

(Decree.)

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

September Term, 1959

No. 16225

DYESTUFFS AND CHEMICALS, INC., *Petitioner,*

vs.

ARTHUR S. FLEMMING, Secretary of Health, Education and Welfare, *Respondent.*

Petition for Review of Order of Secretary of Health, Education and Welfare.

This cause came on to be heard on the Petition for Review of the Final Order of the Secretary of Health, Education and Welfare entitled "In the Matter of amending the color-certification regulations with respect to FD&C Yellow No. 1, FD&C Yellow No. 2, FD&C Yellow No. 3 and FD&C Yellow No. 4" entered February 6, 1959, and was argued by counsel.

On Consideration Whereof, It is now here Ordered, Adjudged and Decreed by this Court that the Final Order of February 6, 1959, in this cause, be, and it is hereby, affirmed.

And it is further Ordered by this Court that the Petition for review in this cause be, and the same is hereby, dismissed.

October 30, 1959.

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JAMES R. BROWNING, Clerk

No. 654

In the Supreme Court of the United States

OCTOBER TERM, 1959

DYESTUFFS & CHEMICALS, INC., PETITIONER

v.

ARTHUR S. FLEMMING, SECRETARY OF HEALTH, EDUCATION, AND WELFARE

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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